west virginia department of environmental protection

Division of Water and Waste Management
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Earl Ray Tomblin, Governor
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January 31, 2012

Jim and Della Tennant
15 Mansion Blvd.
Parkersburg, WV 26101

CERTIFIED MAIL RETURN RECEIPT REQUESTED

Re: WV/NPDES Permit No. WV0001279
Consent Order No. 7418 Comments

Dear Mr. and Mrs. Tennant:

This correspondence is in response to your comment letter dated December 13, 2011 regarding draft Consent Order No. 7418 for WV/NPDES Permit No. WV0001279 issued to the Dupont - Washington Works facility. Comments are summarized first in bold italics followed by the agency's responses.

1. ***Comment: The order should not allow Dupont to discharge the new compound until all of the treatment upgrades are completed.***

   The existing treatment employed at the facility will provide treatment of the new compound. The additional treatment proposed by the permittee will enhance treatment and allow for less frequent change-outs of activated carbon from the existing carbon bed system. Regardless of the treatment enhancements to be made by the permittee, the effluent limitations for the new compound are effective immediately upon issuance of the consent order and will be protective of the water quality standards and designated uses of the Ohio River.

2. ***Comment: The order shouldn't be issued without explaining the new compound, its effects on people and the environment, its toxicity, and how the DEP arrived at the safety levels and monitoring requirements for the new compound.***

   The new compound (C3 Dimer Acid/Salt) is a new fluoropolymer compound that Dupont is representing as an ultimate replacement for the existing fluoropolymer known as C8 (or PFOA, perfluorooctanoic acid). Dupont entered into a Toxic Substances Control Act Consent (TSCA) Consent Order with the U.S. EPA in January 2009 which granted Dupont approval, under conditions set forth in the TSCA Consent Order, to manufacture, process, and distribute the new compound. The U.S. EPA TSCA Consent Order

prescribed certain requirements and toxicological studies regarding the new compound. In 2011, Dupont provided toxicological data to the WV DEP as well as plans to begin production of the new compound. As noted, the U.S. EPA TSCA Consent Order prescribes certain requirements on Dupont regarding the new compound and those requirements are required to be achieved independent of Consent Order No. 7418 that is proposed by the WV DEP. The WV DEP reviewed the toxicological information provided by Dupont regarding the new compound. Chronic studies which provide data regarding long-term impacts are still being conducted by Dupont on the new compound and are not yet complete. Although such long-term studies are preferable, toxicological data from shorter-term (e.g. subchronic) studies may be used to determine a suitable toxicity criterion, provided an additional safety factor is applied. Thus the agency utilized subchronic (90 day) data developed by DuPont in support of its PMN submission (subsequent to the 2009 TSCA Consent Order), incorporating appropriate safety/uncertainty factors, in order to calculate a risk-based Drinking Water Equivalent Level (DWEL) for the new compound. As a courtesy, the agency has attached a memo prepared by a WV DEP toxicologist which summarizes how the agency arrived at the risk-based DWEL. As the requisite chronic studies are completed in the future, the agency will revisit and revise, as necessary, the value indicated in the WV DEP Consent Order. However, based on the information provided and all other information available at this time, the WV DEP has determined that the requirements imposed will be protective of West Virginia's narrative water quality standards found in 47 CSR 2, Section 3 of the West Virginia Legislative Rules.

3. ***Comment: A public hearing is requested.***

   The agency received three (3) requests for a public hearing regarding the consent order. Based on the limited comments received by the agency and resultant limited requests for a public hearing, the agency has determined that a public hearing is not warranted.

The agency would like to thank you for taking the time to submit comments.

The Division of Water and Waste Management issued Consent Order No. 7418 on January 31, 2012. Thank you for your interest in this order.

Sincerely,

Scott G. Mandirola
Director

Enclosure

cc w/enclosure: U.S. EPA Region 3
Env. Inspector Supervisor
Env. Inspector

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MEMORANDUM

To: Yogesh Patel
Matthew Sweeney

From: Lawrence P. Sirinek, Ph.D. LPS

Date: January 31, 2012

Subject: DuPont GenX Toxicity

CC: Pat Campbell
Scott Mandirola
Ken Ellison
Don Martin

I have completed my review of the documentation provided by DuPont regarding the toxicity of GenX Compound A and Compound B. As I requested redacted documents, the identities and chemical differences between the substances were not provided; however, most of the toxicological studies appear to involve compound B. For this reason I have focused my discussion on this compound. The relevance of the different compounds as they relate to permitted discharges should be clarified with DuPont.

With regard to ecological endpoints, I concur with the points provided in the documents provided by DuPont. Thus, 4.2 mg/L, reported as the 21 day NOEC (no observed effect concentration) for *Daphnia magna* seems to be an appropriate endpoint for use in determining discharge levels that would protect aquatic receptors.

With regard to human health effects, there were no data from chronic studies performed in either rats or primates contained in the material provided by DuPont. Chronic studies in both rats and mice are apparently ongoing, however data was not provided. While these data would be preferable, derivation of an appropriate toxicity criterion for human health can be based on a subchronic (90 day) study performed in rats. In this particular study, DuPont indicates a NOAEL (no observed adverse effect level) at 10 mg/kg/day, based on evidence of regenerative anemia in males at 100 mg/kg/d and females at 1000 mg/kg/d. Other effects were reported, but are likely attributable to mechanisms that are often considered irrelevant to potential human toxicity (e.g. PPARα agonists).

With regard to the NOAEL, it must be noted that male rats exposed at this concentration (10 mg/kg/day) did exhibit significant decreases in erythrocyte (red blood cell) counts, hematocrit, and hemoglobin levels that are also indicative of anemia. DuPont considers the anemia

described by these parameters as non-adverse in this group, since the animals lacked evidence of compensatory erythrocyte production (e.g. elevated reticulocyte counts). On the other hand, while the reticulocyte counts were not significantly elevated in this group, there was a clear, dose-dependent trend in the mean reticulocyte count at week 13. Unfortunately it cannot be determined whether continued dosing beyond this time point would have resulted in more dramatic indications of a compensatory response, or whether the impact was sufficiently limited at the 10 mg/kg/day dose, such that no compensatory response was needed. Absent more definitive data, the depressed red cell counts, hematocrit and hemoglobin levels should be sufficient to constitute a health-protective endpoint for purposes of assessing the potential impacts from chronic exposure to the test compound. Additional consideration should be made when results of the chronic study are provided.

On the basis of a revised NOAEL of 0.1 mg/kg/day, and applying relevant uncertainty factors for chronic to subchronic extrapolation (10) and rat to human extrapolation (10), the oral reference dose (RfD_O) = 0.001 mg/kg/day. Based upon this value, a reasonable risk-based drinking water equivalent level (DWEL) assuming total intake of the substance from a contaminated source would be 35µg/L. As discussed in subsequent communications, a source adjustment of 50% could reasonably be applied to this value to allow for potential intake from other sources. Use of this adjustment would result in a final DWEL of 18 µg/L. Based upon the information provided by DuPont, I believe this value would protect both human health and the environment.

I hope this discussion is helpful. Please contact me should you require further discussion or clarification.